SEP 2 2 2009

K091343

Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92 for the SurgiVision MRI Neuro Surgical Drape and accessories.

1. **Company making the submission:**

Name of Owner:	**SurgiVision, Inc.**
Address:	**5 Musick** **Irvine, CA 92618**
Telephone:	**949-900-6833**
Fax:	**949-900-6834**
Contact:	**Edward Waddell**
E-mail:	**Ewaddell@surgivision.com**
Correspondent:	J. Harvey Knauss
Address:	11984 South Evelyn Circle Houston, Texas 77071-3404
Telephone:	713-723-4080
Fax:	713-723-0786
E-mail:	harvey.knauss@gmail.com

2. **Device Name:**

Common Name:	Surgical Drape and accessories
Proprietary Name:	MRI Neuro Surgical Drape and accessories
Regulation Number:	878.4370
Product Code:	KKX

3. **Predicate Device:**

Surgical Concept Designs Surgical Drape, K081476

4. **Intended Use Statement:**

The MRI Procedure drape is intended to provide a sterile, disposable covering of the MRI instrumentation during surgical procedures conducted under MR imaging. The Device Number is 100. Accessories: Grommet, grommet tool and trackball cover.

5. **Description of Device:**

The MRI Procedure Drape is composed of urethane film, polyethylene EVA copolymer film and polypropylene nonwoven material, creating a sterile barrier for a surgical procedure. The construction includes a suspension system that allows the clear film area to move with the patient as they are moved in and out of the MRI scanner bore.

6. **Summary of the technological characteristics of the device compared to the predicate device.**

Characteristic	MRI Neuro Drape	
Classification Regulation	21CFR 878.4370	21CFR 878.4370
Product Code	KKX	KKX
Prescription Device	Yes	Yes
Composition	PE and PP	PE
Sold Sterile	Yes	Yes
Sold Single Use	Yes	Yes
MRI Safe	Yes	Unknown

7. **Testing:**

Testing to applicable Standards has been completed with positive outcomes.

Top level of testing performed:

- Sterilization and Shelf Life
- Performance Testing – Bench, including tensile, tear resistance, slow rate penetration and flammability

8. **Rx or OTC:**

The MRI Procedure Drape is an Rx prescription device per 21 CFR Subpart D.

9. **Conclusions:**

The MRI Procedure Drape is equivalent to the predicate device in the scope of practical application, effectiveness at this application, and ensuring the safety of its subject.

The MRI procedure drape does not raise any new safety or effectiveness issues.

SurgiVision, Inc.

Edward Waddell
Director of Quality and Regulatory

Date: 9/2/09

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 22 2009

SurgiVision, Incorporated
C/O Mr. Harvey Knauss
Delphi Consulting Group
11874 South Evelyn Circle
Houston, Texas 77071

Re: K091343
Trade/Device Name: MRI Neuro Drape
Regulation Number: 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: September 2, 2009
Received: September 3, 2009

Dear Mr. Knauss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K091343

Device Name: MRI Neuro Drape

Indications for Use: The MRI Neuro Surgical Drape is intended to provide a sterile, disposable covering of the MRI instrumentation during surgical procedures conducted under MRI imaging. The Device Number is 100. Accessories: Grommet, grommet tool and trackball cover.

✓ Prescription Use (Part 21 CFR 801 Subpart D) AND/OR Over-The Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Shuba K Murphy MD

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091343